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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,041

07/03/2006

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EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

NOTIFICATION DATE

DELIVERY MODE

09/07/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,041	Applicant(s) MIYAWAKI ET AL.	
	Examiner CHRISTINA BRADLEY	Art Unit 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 20-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,36,37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/15/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-37 are pending. Claims 1-17 and 20-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/08/2010.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 07/15/2010 was filed after the mailing date of the first action on the merits on 03/15/2010. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The objection to the specification for the use of the trademarks MILLIQ, TRIZOL, TAQ and PYROBEST is withdrawn in view of the amendment filed 07/15/2010.

Claim Objections - withdrawn

4. The objection to claim 18 is withdrawn in view of the amendment filed 07/15/2010.

Claim Rejections - 35 USC § 101 - withdrawn

5. The rejection of claims 18 and 19 under 35 U.S.C. 101 is withdrawn in view of the amendment filed 07/15/2010.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 18, 19, 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

8. MPEP § 2163 states that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Scope of the claimed genus

9. Claims 18 and 19 are drawn DNA encoding SEQ ID NO: 5 or 7, DNA encoding a fluorescent protein with one to ten substitutions, deletions or additions relative to SEQ ID NOs: 5 or 7, DNA comprising SEQ ID NO: 6 or 8, or DNA comprising SEQ ID NO: 6 or 8 with one to thirty substitutions, deletions or additions.

Assessment of whether species are supported in the original specification

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10. Two embodiments of the invention of claims 18 and 19 were reduced to practice at the time of filing. The specification teaches the complete structure of DNA of SEQ ID NOs: 6 and 8 which encodes a fluorescent protein of SEQ ID NOs: 5 and 7, respectively. The specification also teaches distinguishing characteristics of the fluorescent proteins encoded by this DNA. For example, the proteins are derived from *Acropora* sp. and are characterized by having an excitation maximum wavelength of 472 nm, a fluorescent emission maximum wavelength of 496 nm, a molar extinction coefficient of 27,250, a quantum yield of 0.9 and a pH sensitivity pKa of 6.6. For these reasons, the skilled artisan would reasonably conclude that the inventor(s), at the time the application was filed, had possession of SEQ ID NOs: 6 and 8 at the time the invention was filed.

Assessment of whether disclosed species are representative of the claimed genus

11. MPEP § 2163 states that a “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

12. In the instant case, the claims allow for a limited number of substitutions, deletions and additions to SEQ ID NOs: 6 and 8. The claims also allow for DNA encoding a protein with a limited number of substitutions, deletions and additions provided that it is fluorescent. Although the amendment filed 07/15/2010 reduced the scope of the instant claims, the genus is still broad encompassing DNA encoding proteins with any of the 232 positions of SEQ ID NOs: 5 or 7 modified, up to 95.7% identity. Given the breadth of the claimed genus, the two single DNAs reduced to practice are not representative of the genus.

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Identifying characteristics and structure/function correlation

13. In the absence of a reduction to practice of a representative number of species, the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. To meet this requirement in the instant case, the specification must describe the structural, physical and/or chemical properties of a DNA that lead to the claimed function of encoding a fluorescent protein. The instant specification fails to describe a correlation between the structure of the DNA (or the protein encoded by it) and the fluorescent properties of the protein. The specification does not describe which residues make up the chromophore of the protein or how other residues outside of the chromophore influence its spectral properties. The specification does not describe which positions can be changed or modified and in what manner while preserving fluorescence.

14. In the response filed 07/15/2010, Applicants have not pointed to a description in the specification of the residues in SEQ ID NOs: 5 and 7 that are critical for maintaining the claimed physical property of fluorescence. The specification does not necessarily need to describe each and every species in the genus to meet the written description requirement. However, the specification must present the identifying characteristics of the genus. In the instant case, the physical property of the genus, fluorescence, is described and claimed, without a correlation to the structure of the protein or DNA that encodes it. Accordingly, one of ordinary skill in the art

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could not inspect a sequence and determine whether or not it possesses the claimed property of fluorescence.

15. In conclusion, for these reasons, the skilled artisan would not reasonably conclude that the inventor(s), at the time the application was filed, had possession of the full scope of the claimed invention. Only those SEQ ID NOs: 6 and 8 satisfy the written description requirements of 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 18, 19, 36 and 37 are rejected under 35 U.S.C. 102(a) as being anticipated by Karasawa et al. (“Cyan-emitting and orange-emitting fluorescent proteins as a donor/acceptor pair for fluorescence resonance energy transfer.” *Biochem. J.*, published 5 April 2004, 381, 307-312), as evidenced by GenBank: AB128822.1. Karasawa et al. teach a nucleotide that is 100% identical to instant SEQ ID NO: 6, which encodes an amino acid sequence that is 100% identical to instant SEQ ID NO: 5, as evidenced by GenBank AB128822.1. The protein is a fluorescent protein.

18. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See

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MPEP § 201.15. The translation of Application No. 2003-170326 filed 07/15/2010 is insufficient to overcome the rejection because said application does not support the full scope of claims 18, 19, 36 and 37. Application No. 2003-170326 teaches a fluorescent protein consisting of instant SEQ ID NO: 5 and the DNA encoding it but does not teach a fluorescent protein consisting of SEQ ID NO: 7 or DNA encoding it.

Claim Rejections - 35 USC § 102 - withdrawn

19. The rejection of claims 18 and 19 under 35 U.S.C. 102(e) as being anticipated by Matz et al. (US 7,160,698) is withdrawn in view of the amendment filed 07/15/2010.

20. The rejection of claims 18 and 19 under 35 U.S.C. 102(e) as being anticipated by each of the following patents or publications is withdrawn in view of the amendment filed 07/15/2010: U.S. Patent No. 7,060,869, U.S. Patent No. 7,226,993, U.S. Patent No. 7,345,157, U.S. Patent No. 7,504,491, U.S. Patent No. 7,541,451, U.S. Patent No. 7,547,528, U.S. Patent No. 7,375,201; and US 2005/0208624.

21. The rejection of claims 18 and 19 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,998,204 is withdrawn in view of the amendment filed 07/15/2010.

22. The rejection of claims 18 and 19 under 35 U.S.C. 102(a) and (e) as being anticipated U.S. Patent No. 6,627,449 is withdrawn in view of the amendment filed 07/15/2010.

Claim Rejections - 35 USC § 103 - withdrawn

23. The rejection of claims 18 and 19 under 35 U.S.C. 103(a) as being unpatentable over Papina et al. ("Separation of highly fluorescent proteins by SDS-PAGE in Acroporidae corals," *Comparative Biochemistry and Physiology Part B*, 131 (2002) 767-774) in view Gibbs et al. (US 2004/0110225) is withdrawn in view of the arguments filed 07/15/2010.

Double Patenting - withdrawn

24. The rejection of claims 18 and 19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of the following patents is withdrawn in view of the amendment filed 07/15/2010: claims 1-21 of U.S. Patent No. 5,998,204; claims 1-27 of U.S. Patent No. 6,627,449; claims 1-27 of U.S. Patent No. 7,060,869; claims 1-8 of U.S. Patent No. 7,226,993; claims 10-16 of U.S. Patent No. 7,247,449; claims 1-9 of U.S. Patent No. 7,375,201; claims 1-4 of U.S. Patent No. 7,345,157; claims 1-9 of U.S. Patent No. 7,504,491; claims 1-8 of U.S. Patent No. 7,541,451; and claims 1-9 of U.S. Patent No. 7,547,528.

25. The provisional rejection of claims 18 and 19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over each of the following copending applications is withdrawn in view of the amendment filed 07/15/2010: claims 14-19 of copending Application No. 11/042,158; claims 7-10 and 13-18 of copending Application No. 11/569,275; claims 8 and 11-13 of copending Application No. 10/561,040; claims 4-6 of copending Application No. 12/569,464; claims 1-6 of copending Application No. 12/463,271; and claims 4, 7, 10, 11 and 18 of copending Application No. 10/581,551.

Conclusion

26. No claims are allowed.

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia Tsang/

/Christina Marchetti Bradley/

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Supervisory Patent Examiner, Art Unit 1654

Examiner, Art Unit 1654

cmb